DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953813

July 12, 2000

Tai K. Lan, Owner
Dong Ling Sprouts and Produce Co.
2400 Grant Avenue
San Lorenzo, CA 94580

WARNING LETTER

Dear Mr. Lan:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 2400 Grant Avenue, San Lorenzo, California on May 15, 17, 18, 24 and June 12, 2000.

The inspection revealed lack of implementation of the recommended practice of microbial testing of spent irrigation water from your sprout processing. This causes your firm's sprouts to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are produced under insanitary conditions that may render them injurious to health. The conditions under which the sprouts are produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm.

Furthermore, the inspection revealed insanitary practices and conditions which cause all foods on your premises to be adulterated within the meaning of Section 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth. Laboratory analyses of samples collected by FDA during the inspection confirm that the mung beans and soybeans in Containers #1 and #3 are adulterated within the meaning of Section 402(a)(4) of the Act because they have been held under insanitary conditions whereby they may have been contaminated with filth. Laboratory analyses of samples also confirm that the foods are adulterated within the meaning of Section 402(a)(3) of the Act in that they consist in part of a filthy substance.

The following is a list of the insanitary practices, conditions, and findings observed by Investigators Joan T. Briones and Bradley J. Maunder:

1. LACK OF ADEQUATE PEST CONTROL PROGRAM:
   a. Two live mice were observed in Container #3, caught in glue traps located near pallets of mung beans.
   b. Bags of mung beans in both Containers #1 and #3 were observed to bear stains, rodent excreta pellets, animal hairs, and gnawed product.
   c. Bags of soybeans in Container #3 were observed to bear rodent excreta pellets and animal hairs.
   d. A dead rat and a dead mouse were observed near the south end of the storage area and near the north end of the storage area, respectively.
   e. Numerous rodent excreta pellets were observed along the east wall across from the boiler, near the south wall of the storage area, at the left and right sides of door at the south wall of the storage room, adjacent to the east wall of the storage area, and on a pile of wood in the east end of the storage area.

2. POOR EMPLOYEE PRACTICES
   a. Employees of the firm were observed near the sprout packaging area without hair restraints.
   b. Open soda containers were observed adjacent to the south end of the shaker table in the production area.

3. FAILURE TO MAINTAIN SANITARY OPERATIONS
   The following observations were made after equipment cleanup, indicating inadequate clean-up procedures:
   a. A pink gelatinous residue on two-pronged cylinders on the sprout processing equipment.
   b. Dark residues in the corners of the sprout tank, on the rubber gaskets that seal stainless steel sprout tank components, on the inside of two metal mesh baskets intended to screen out bean shells during sprout processing, and under the end of the sprout shaker table.
   c. A white gelatinous residue inside screen holes on the sprout shaker table.
   d. A buildup of a brownish material on the ceiling of the sprout cooler.

4. FAILURE TO KEEP EQUIPMENT AND UTENSILS CLEAN AND IN GOOD REPAIR
   a. Wires were observed to be used to secure various components of the sprout processing line.
   b. Rusted components were observed on the sprout processing equipment.
   c. The conveyor belt on the sprout processing equipment was observed to be split.

5. FAILURE TO HAVE SANITARY FACILITIES AND CONTROLS
   a. "Dead legs" were observed in the overhead potable water supply lines
      (1) 80 ft "dead leg" extending from north of Hot House #5 to the east end of the facility.

(2) 30 ft "dead leg" extending from the bathroom at the east end of the facility to the ice machines.

b. The water supply hoses to the sprout tank were observed to lack back flow prevention.
c. No hand towels were observed in the bathroom at the west end of the facility.

6. FAILURE TO MAINTAIN PLANT AND GROUNDS
   a. Two unscreened openings of 12" in diameter and 4" in diameter were observed in the facility ceiling, adjacent to the Hot Houses.
   b. Uncovered drains or drains with damaged screens were observed throughout the facility.
   c. Gaps ranging in size from ½" to 2" were observed along the bottom and/or sides of doors leading to outside the facility.

7. FAILURE TO HAVE ADEQUATE PROCESSES AND CONTROLS
   a. One hundred (100) 50-lb bags of soybeans and 130 bags 5-lb bags of mung beans, all of which bore signs of rodent activity (stains, gnaw holes, and rodent excreta pellets), were transferred from Container #3 to inside the facility for processing despite knowledge that they were contaminated.
   b. The hardware on the doors of Containers #1 and #3 were observed not to align properly such that the doors do not close adequately, allowing a gap of 2" and 4", respectively, near the bottom of the doors.
   c. The facility's west roll-up door was observed to be open throughout the entire inspection.
   d. The door leading to the vegetable cooler was observed to be open throughout the entire inspection.
   e. Piles of wood and miscellaneous building supplies were observed in the storage space of the facility.
   f. The recommended guidance of microbial testing of spent irrigation water as a preventive control for pathogens has not been implemented.
   g. An employee was observed to move plastic containers of sprouts from the Hot House to the wash tank by sliding them along the production room floor. The employee then loaded sprouts from the plastic containers into the wash tank by upending the plastic containers with a gloved hand at the bottom of the plastic container, then transferred the sprouts into the wash tank by gloved hand without washing or sanitizing the glove.
   h. The bottoms of containers used to hold sprouts during various stages of processing were routinely sanitized in a solution of calcium hypochlorite and water, then placed directly on the floor, and filled with sprouts which were subsequently upended into the wash tank.

At the conclusion of the inspection, the insanitary practices and conditions and the lack of implementation of currently recommended practices were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You are responsible for ensuring that your facility operates under Good Manufacturing Practices, codified under Title 21, Code of Federal Regulations, Part 110 (21 CFR 110).

A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed. FDA currently recommends the treatment of pre-washed seed with 2% (20,000 ppm available chlorine) calcium hypochlorite solution for 15 minutes at room temperature with continuous agitation. The ratio of five (5) pounds of seed in one gallon 2% calcium hypochlorite solution is recommended. See enclosed EPA Reg. #1258-427.

We note that you add sodium metabisulfite to your wash water during sprout processing. Please be aware that, per Title 21, Code of Federal Regulations, Part 182.3766, sodium metabisulfite should not be used on vegetables that are intended to be served raw to consumers. For your information, your sprouts are adulterated per Section 402(a)(2)(C)(i) of the Act in that they bear a food additive that is unsafe within the meaning of Section 409 of the Act.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Darrell Lee
Acting District Director
San Francisco District